

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

> Drexdal Pratt Division Director

October 14, 2014

Dee Jay Zerman
Director of Regulatory Planning
UNC Hospitals
Hedrick Building
211 Friday Center Drive, Suite G015
Chapel Hill, NC 27517

Exempt from Review-Replacement Equipment

Facility or Business: University of North Carolina Hospitals

Project Description: Replace existing heart lung bypass machine

County: Orange FID #: 923517

Dear Ms. Zerman:

In response to your letter of October 8, 2014, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S. 131E-184(a) (7). Therefore, you may proceed to acquire, without a certificate of need, the Sorin S5 system to replace the Sarns/Terumo 8000 pump (Serial # S/N 1498 (base) system). This determination is based on your representation that the manufacture of the equipment to be replaced is discontinuing this product and will not be able to service the old equipment. The School of Medicine has approached the hospital requesting use of the equipment for animal research. The total inventory of UNC Hospital's operational heart lung bypass machines will not increase at any time either before or after project completion. Further, please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Branch with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Construction Section of the Division of Health Service Regulation to determine if they have any special requirements for the proposed project.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a



Certificate of Need Section

Dee Jay Zerman October 14, 2014 Page 2

separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,

F. Gene DePorter, Project Analyst

Martha J. Frisone, Interim Chief Certificate of Need Section

ce: Medical Facilities Planning Branch, DHSR

Construction Section, DHSR (Not Hospice Home Care/ Home Health) Acute and Home Care Licensure and Certification Section, DHSR





Hedrick Building 211 Friday Center Drive, Suite G015 Chapel Hill, NC 27517

October 6, 2014

Mr. F. Gene DePorter, Project Analyst Certificate of Need Section Division of Health Service Regulation, DHHS Mail Service Center 2704 Raleigh, NC 27699-2704

RE: Request for Exemption / Replacement of an existing heart lung bypass machine / UNC Hospitals

Dear Mr. DePorter:

UNC Hospitals is planning to replace an existing heart lung bypass machine and is requesting a determination that the replacement of this equipment is exempt from review pursuant to NCGS §131E-184(7). The existing heart lung bypass machine was placed into service in 1999, and remains in use. The age of this machine is making it difficult to obtain replacement parts for repairs.

We are supplying the following information that the CON Section has requested in the past as a part of its general information request for an equipment replacement exemption.

1. A comparison of the existing and replacement equipment, using the format in the following table:

Equipment Comparisons

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Heart/Lung machine	Heart/Lung machine
Manufacturer of Equipment	Sarns/Terumo	Sorin
Tesla _. Rating for MRIs	N/A	N/A
Model Number	Model 8000	Sorin S5
Serial number	S/N 1498 (base)	Not yet available
Provider's Method of Identifying Equipment	By model & serial #s	By model & serial #s
Specify if Mobile or Fixed	Portable	Portable
Mobile Trailer Serial Number/VIN #	Not applicable	Not applicable
Mobile Tractor Serial Number/VIN #	Not applicable	Not applicable
Date of Acquisition of Each Component	1999	Projected 2014
Does Provider Hold Title to Equipment or Have a	UNC Hospitals owns the	UNC Hospitals will own
Capital Lease?	equipment	the equipment

Specify if Equipment Was/Is New or Used When Acquired	New	Will be new
Total Capital Cost of Project (Including Construction, etc.) <see 4="" exhibit=""></see>	Approx. \$101,005	\$240,326
Total Cost of Equipment	Approx. \$101,005	\$240,326
Fair Market Value of Equipment	N/A (no trade-in value)	\$240,326
Net Purchase Price of Equipment	N/A	\$240,326
Locations Where Operated	UNC Hospitals	UNC Hospitals
Number of Days In Use/To be Used in N.C. Per Year	365 days	365 days
Percent of Change in Patient Charges (by Procedure)	N/A	No change
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	No change
Type of Procedures Currently performed on Existing Equipment	Open heart surgery	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Open heart surgery

2. A description of the basic technology and functions of the existing and replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or capable of being used.

Response: The machine to be replaced is a Sarns Terumo Model 8000 pump. Exhibit 1 contains the original brochure and the original quote for the existing Sarns 8000. The original purchase order is not available. UNC Hospitals plans to replace this pump with the Sorin S5 pump. The current equipment and the replacement equipment will perform the same basic functions. Both are pumps which during open heart surgery take over the pumping action of the heart. Attached to the heart lung machine is an oxygenator (not included in the purchase) which performs the functions of the lungs. The replacement equipment has computer control of the pump heads which offer safety features to reduce the potential of strokes. The electrical components in the replacement equipment are protected from damage from fluids. The manufacturer is no longer producing the existing Sarns 8000, and as a result will soon discontinue support for the Sarns 8000 machines.

3. Brochures or letters from the vendors describing the capabilities of the existing equipment and the replacement equipment.

Response: A copy of a brochure and the original quote for the existing Sarns 8000 is attached as Exhibit 1. The original purchase order is not available. A copy of a brochure from the vendor describing the proposed replacement Sorin S5 pump is attached as Exhibit 2.

4. A copy of the purchase order for the existing equipment, including all components and original purchase price.

Response: A copy of the original brochure and quote is attached as Exhibit 1. The original purchase order is not available.

5. A copy of the title, if any, for the existing equipment or the capital lease for the existing equipment.

Response: Not applicable. The existing equipment does not have a title and is not leased.

6. If the replacement equipment is to be leased, a copy of the proposed lease that transfers substantially all the benefits and risks inherent in the ownership of the equipment to the lessee of the equipment, in accordance with criteria in Generally Accepted Accounting Principles (GAAP).

Response: Not applicable. The replacement equipment will not be leased.

7. If the replacement equipment is to be purchased, a copy of the proposed purchase order or quotation, including the amount of the purchase price before discounts and trade-in allowance.

Response: A copy of the quote received from Sorin for the replacement pump is attached as Exhibit 3. The existing machine has no trade-in value because the vendors are not interested in taking possession of the existing equipment due to its age.

8. A letter from the person taking possession of the existing equipment that acknowledges the existing equipment will be permanently removed from North Carolina, will no longer be exempt from requirements of the North Carolina Certificate of Need law, and will not be used in North Carolina without first obtaining a new certificate of need.

Response: As a State Agency we have two options for the disposal of equipment. The first is by trade-in on the purchase of replacement equipment. However, due to the advanced age of this equipment Sarns is not interested in taking possession of this equipment. The second option available to us as a State Agency is disposal through State Surplus Property. The School of Medicine has approached us to use the surplused equipment for laboratory animal research. Upon replacement, the existing Sarns 8000 pump will be surplused to the School of Medicine. Since this specific machine is being phased out by the manufacturer, the vendor will no longer guarantee replacement parts and will no longer execute full service contracts for repair of the machine. The equipment is still useful for laboratory animal research.

9. Documentation that the existing equipment is currently in use and has not been taken out of service.

Response: UNC Hospitals currently has four heart lung bypass machines in use as identified on our most recent licensure Renewal Application form. See Exhibit 4 for a copy of the page of the 2014 Licensure Renewal Application form pertaining to heart-lung bypass machines.

Exhibit 5 contains a completed 'Proposed Total Capital Cost of Project' form which projects the total capital cost of this replacement project to be \$240,326 for the Sorin S5 machine. The total project cost includes all costs required to make the unit operational.

Please do not hesitate to contact me at 984-974-1210 if you need any additional information. Thank you for your prompt consideration of this matter.

Sincerely,

Dee Jay Jerman Director of Regulatory Planning

UNC HCS

Exhibit 1

Sarns a	LTH CARE nd CDI Products CKSON RD. BOR, MI 48103	DATE:	5/26/99	EXISTING MACHINE
	4145/800-262-3304 4-741-6181	,		
TO:	Franklin Boone Sr. Chief of Perfusion	# PAGE (INCLUD	5 NG COVER	₹)
	UNC Hospital	FAX NO:	919-966-34	175
FROM:	Mike Cuddington Contract Administrator	PHONE:	800-262-33 734-741-63	
REFERE	NCE: Proposal No. 201206			
MESSAG	Per your request please see the updated proposed current date. If you have any questions please to			
			1000000	
	Sincerely,			•
	Mik e Cuddington			

3M Proposal

May 26, 1999

Franklin Boone, Sr. Chief Of Perfusion UNC Hospital 101 Manning Drive Chapel Hill, NC 27514

Proposal No. 201206

For 3M ™ Sarns™ 8000 Perfusion System

Qty	Product No.	Description-		Amount
1	98-0702-0644-0	16401 Base 5 Unit 115V	\$15,000.00	\$15,000.00
5	98,0702-0647-3	16402 Roller Pump 115V	\$10,600.00	\$53,000.00
1	98 0702-0660-6	16404 Safety Monitor	\$0.00	\$0.00
1	98-0702-0842-0	5773 Air Sensor 3/8x3/32	\$0.00	\$0.00
1	98\0702-0860-2	5799 Level Sensor Pads 100/Pk	\$0.00	\$0.00
1	98-0702-0267-0	164278 Ultrasonic Gel	\$0.00	\$0.00
1	98-0702-0655-6	16413 Arterial Monitor	\$4,000.00	\$4,000.00
1	98-0702-0654-9	16414 Cardioplegia Monitor	\$5,000.00	\$5,000.00
1	98-0702-0692-9	16421 Monitor Mounting Arm	\$690.00	\$690.00
1	98-0702-0657-2	16416 Pulse Module System 8000	\$5,500.00	\$5,500.00
1	98-0702-0722-4	16422 Battery Module 115V	\$7,500.00	\$7,500.00
1	98-0702-0664-8	16420 Lamp System 8000	\$690.00	\$690.00
1	98-0702-0659-8	16418 Electronic Occluder	\$6,650.00	\$6,650.00
1	78-8066-6721-4	16433301 Pressure Transducer	\$1,400.00	\$1,400.00
1	98-0702-0211-8	16066100 Pressure Mntrg Kit	\$0.00	\$0.00
1	98-0702-0353-8	22300030 Transducer Holder	\$0.00	\$0.00
1	98+0702-0252-2	164235 Sechrist Blender	\$1,575.00	\$1,575.00
		TOTAL	_	\$101,005.00

3M

Health Care Cardiovascular Systems SARNS^M AND CDI^M PRODUCTS 6200 Jackson Road PQ Box 1247 Ann Arbor, MI 48103-1247 USA

800 521 2818 Tel 313 663 4145 Tel 800 292 6551 Fax Proposal No. C005624 5/26/99

Page: 2

Warranty

Please note that this equipment comes with a warranty covering all repairs, parts and labor for the first 12 months following delivery. Prices contained in this proposal are valid for 60 days.

Terms

The terms of this proposal are not 30 days, F.O.B., Ann Arbor, Michigan. (Please allow 45 days from receipt of the order to commence shipment.)

If you have any questions regarding this proposal, you may contact either of the following persons at 800-262-3304: Randy D. Pence, Cardiovascular Systems account representative, extension 6028

Mike Cuddington, Contract Administrator, extension 6382



Health Care
Cardiovascular Systems
SARNSTM AND CDITM PRODUCTS

6200 Jackson Road PO Box 1247 Ann Arbor, MI 46103-1247 USA

800 521 2818 Tel 313 663 4145 Tel 800 292 6551 Fax

3M Health Care/3M Health Care Standard Cardiovascular Products

Terms and Conditions

1. Invoicing and Payment:

All prices are F.O.B. 3M Health Care, point of shipment (hereafter referred to as 3M Health Care) unless otherwise stated in the proposal. All invoices will be dated at or after the date of shipment. All invoices are payable in full within thirty (30) days of the date of invoice.

2. Shipment and Risk of Loss:

3M Health Care makes every effort to meet any shipping dates specified in Buyer's purchase orders, but 3M Health Care does not guarantee to meet any particular shipping deadlines. 3M Health Care will, however, promptly notify Buyer of any delays in processing Buyer's order. Buyer's only remedy for late shipment is to cancel the order. A written notice of cancellation must arrive at 3M Health Care before the Product is actually shipped. Unless instructed otherwise in writing, 3M Health Care will ship via the most economical route and method available, freight prepaid and added to the invoice. Risk of loss passes to Buyer at the F.O.B. point. Title transfers only when Buyer has fully paid for the products.

3. Excusable Delay:

3M Health Care makes every effort possible not to delay your shipment. However, we cannot be held responsible due to causes beyond 3M Health Care reasonable control.

4. Limited Warranty; Remedies Limited:

3M Health Care will repair or replace free of charge any part found to be defective in workmanship or material during one year from the date of shipment. This warranty does not apply to filters, light bulbs, fuses or other expendable items, or to those parts damaged by improper use or by accident. Any parts found to be defective due to lack of maintenance in accordance with 3M Health Care Operators Manuals, or as a result of unauthorized repair, will be repaired or replaced at service rates in effect at that time. This warranty is expressly in lieu of all other warranties expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose. 3M Health Care shall not be liable under any circumstances, for any consequential, incidental, or indirect damages or expenses associated with this warranted product or its use.

5. Buver's Duty to Inspect:

Buyer will promptly inspect any shipment of Products received from 3M Health Care and will promptly notify 3M Health Care. The notice must specify the defects in detail; any defect present but not specified is waived. After sending the notice, Buyer will follow 3M Health Care return



goods policy then in effect, or any specific and reasonable instructions which 3M Health Care may issue. Buyer will allow 3M Health Care to inspect any allegedly defective goods at Buyer's site. For any goods which 3M Health Care determines are defective, Buyer will follow 3M Health Care instructions and either return the goods to 3M Health Care, with 3M Health Care responsible for the return freight, or dispose of the goods in a safe manner (approved by 3M Health Care), at no charge to 3M Health Care. Any goods not rejected within thirty (30) days of delivery are accepted.

6. Use of 3M Health Care Names and Trademarks:

Buyer will make no use whatsoever of 3M Health Care name without 3M Health Care written permission. The decision to grant or withhold permission is within 3M Health Care sole discretion. Buyer will not use or reproduce any of 3M Health Care trademarks in any manner without 3M Health Care prior written approval. To request this approval, Buyer must forward to 3M Health Care a complete and accurate specimen copy of the proposed use. If in its sole discretion, 3M Health Care chooses to approve the use, the use is subject to any revisions which 3M Health Care may choose to make on the specimen.

7. No Assignment OR Delegation:

Buyer may not assign its rights or delegate its duties under these Terms and Conditions.

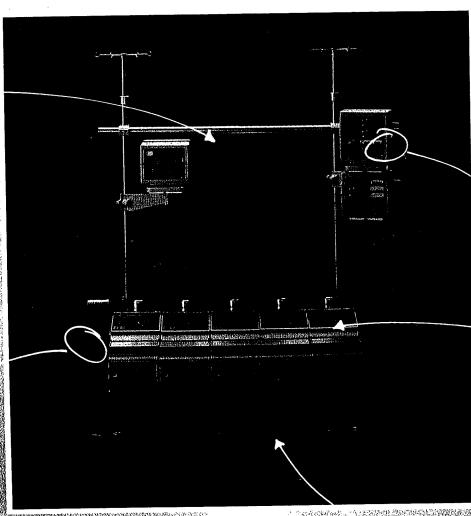
8. Entire Agreement; No Waiver; Governing Law:

These Terms and Conditions state the complete understanding between 3M Health Care and Buyer on this subject and replace any previous statements, communications or understandings, whether oral or written. Any reference to Buyer's purchase order number is solely a matter of administrative convenience to Buyer. These Terms and Conditions cannot be modified except by a signed writing. A course of dealing or of performance does not effect a waiver or modification unless ratified in writing. A party's failure to exercise a right in one instance does not waive that party's right to later exercise that right. Any questions, claims or disputes concerning these Terms and Conditions or this sale are governed by the laws of Delaware.

Build a system to your specs.

hell Instrument frag

Liveria Apellichionie Ocalveo



Yes II de week the condigreção worker

Took orays.

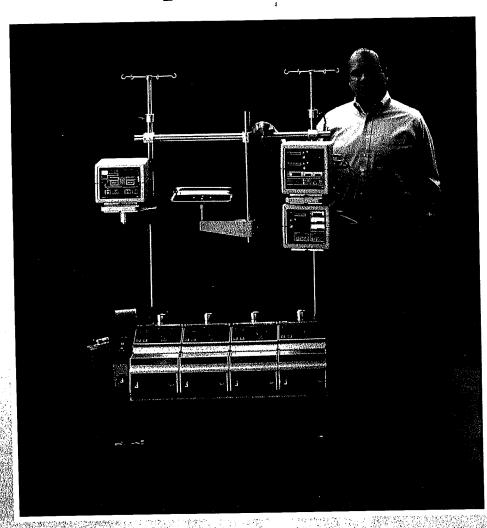
Sarns: 8000 modular perfusion system



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Build your own Sarns™ 8000 modular perfusion system.





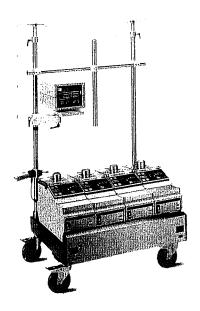
Start with a solid foundation...

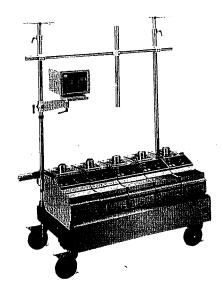
This **flexible**, modular perfusion system offers a four- or five-pump base with easily interchanged pumpheads. The Sarns 8000 modular perfusion system can be upgraded after purchase to include additional equipment as needed.

Safety monitoring is achieved with air bubble and level detection modules. Under specific arterial pressure alarm conditions, the safety module stops both the arterial and cardioplegia pumps immediately.

Proven pump design has been used in Sarns perfusion systems for tens of thousands of open-heart surgeries. The base has been designed to accommodate roller or centrifugal pumps at any position. Each pump plugs into its own circuit and can be connected to the safety module.

Attentive service includes installation, set-up, calibration and periodic maintenance by Sarns service experts. Initial product support is backed by a 24-hour helpline and a wide spectrum of service contracts.

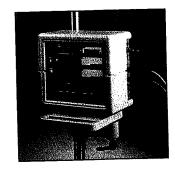




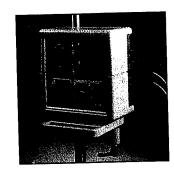


Add the features you want.

Arterial monitor integrates one pressure display, three temperature displays and two separate timers into a single, easy-to-watch module. Specific arterial overpressure conditions will automatically stop arterial and cardioplegia pumps.



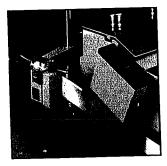
Cardioplegia monitor devotes two pressure displays, three temperature displays and two timers to the cardioplegia circuit. An overpressure alarm will stop the cardioplegia pump for antegrade and/or retrograde delivery.



Automatic battery backup supplies uninterrupted power to two pumps, all safety systems and accessories for 25 minutes. Built into the pump base, the battery conserves scarce OR space.



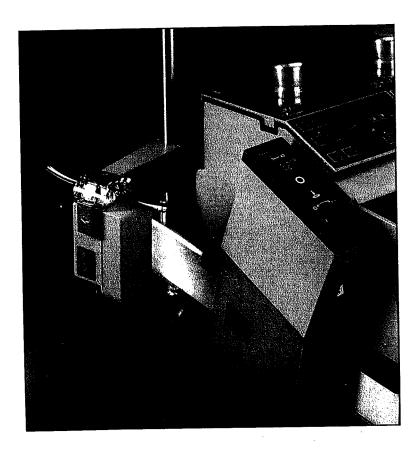
Precise, electronic occluder controls venous flow more accurately and conveniently than conventional means.





Electronic occluder

Sarns 8000 modular perfusion system



Accurate venous flow is controlled with a precise electronic occluder that can be set exactly to achieve any desired occlusion. The occluder responds promptly to any control changes, and the open and close switches have a very fast response time.

Quick self-calibration automatically determines tube wall thickness after the tubing is placed in the occluder head and the close switch is pressed.

Good visibility of the blood flow path is allowed by the see-through tubing clamp.

Convenient mounting and cable storage keep your work zone familiar and uncluttered. Put the occluder on the left or right to suit your needs.

Electronic occluder specifications

Catalog number

16418

Operating parameters

Tubing requirements Minimum

Maximum

1/4 in. (6.4 mm) ID x 1/16 in. (1.6 mm) wall 1/2 in. (12,7 mm) ID x 3/32 in. (2,4 mm) wail

Display range

0-99% of maximum venous flow

Display accuracy

The occluder will display accurately ($\pm 12\%$) only when using 1.2 in, or 3/8 in. ID tubing with the blood at 20 $^{\circ}$ -40 $^{\circ}$ C and with a vertical height of 20–36 in. (50.8–91.4 cm) from the fluid level in the venous reservoir to the level of the patient.

Physical description

	Occluder module	Occluder head
Depth	8.5 in. (21,6 cm)	8.0 in. (20,3 cm)
Width	3.0 in. (7,6 cm)	6.5 in. (16,5 cm)
Height	7.7 in. (19,6 cm)	3.0 in. (7.6 cm)
Weight	3.6 lbs. (1.6 kg)	6.2 lbs. (2.8 kg)
Total system weight (including bracket)	12.6 lbs. (5.7 kg)	

Environmental conditions

Operating temperature

10²-40° C

Relative humidity

<95% relative humidity, noncondensing

For more information about the 8000 electronic occluder, contact your Sarns representative or call **800/521-2818**. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

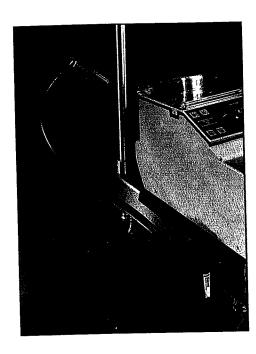
"Sarns" is a registered trademark of 3M.

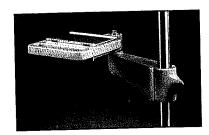
3M Health Care

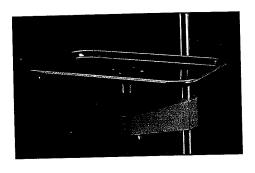
6200 Jackson Road, Ann Arbor, MI 48103 USA Phone: **800/521-2818** or 313/663-4145 FAX: 313/663-7981 Telex: 4930456 SARINC

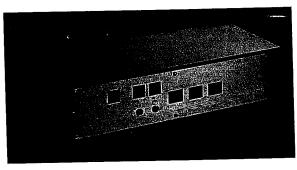
Accessories

Sarns 8000 modular perfusion system









Automatic battery backup provides power to two pumps, all safety systems and accessories for 25 minutes. Switchover from main power to battery backup is automatic and immediate, providing an uninterrupted power supply. The battery unit is built into the pump base to conserve valuable OR space and can be recharged automatically when the system is operating with wall power.

High-intensity quartz lamp can be connected on either end of the base to illuminate the oxygenator. Power to the lamp will be uninterrupted if the battery module is installed.

Positionable instrument tray organizes supplies for more efficient perfusion management.

Adjustable mounting arm for arterial and cardioplegia monitors offers maximum positioning flexibility.

Same of the order

Accessories specifications

Catalog numbers Description Battery module - supplies uninterrupted power to two pumps, all safety systems and accessories for 25 minutes. 16422 115V 16415 220-240V 100V 16420 Lamp Mounting arms Short, with 5/8 in. (1,6 cm) pole 16505801 Long, with 5/8 in. (1,6 cm) pole For 8000 monitors 16505901 16434101 Instrument tray, includes long mounting arm 4404 Writing surface (pole mounted) 16425 Extension Arm 16426 Cross Bar Kit, 3 ft. 16427 Cross Bar Kit, 4 ft. 164235 Blender

For more information about 8000 system accessories, contact your Sarns representative or call **800/521-2818**. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

"Sarns" is a registered trademark of 3M.

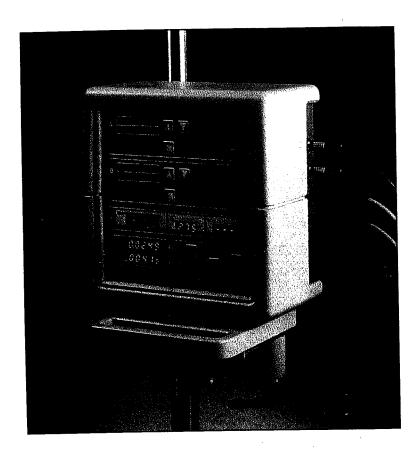
Sarns 3M Health Care

6200 Jackson Road, Ann Arbor, MI 48103 USA Phone: **800/521-2818** or 313/663-4145 FAX: 313/663-7981 Telex: 4930456 SARINC



Cardioplegia monitor

Sarns 8000 modular perfusion system



Dedicated cardioplegia monitor uses two pressure displays, three temperature displays and two timers.

User-set alerts and alarms warn of overpressure or actually stop the cardioplegia pump. The system retains the settings for the next power up.

Automatic pump stop will occur for antegrade and/or retrograde delivery under specific overpressure conditions.

Adjustable audio volume can be set to your preference.

Convenient timers track the length of each cardioplegia infusion as well as time between infusions.

Cardioplegia monitor specifications

Catalog number (Mounting arm ordered separately)

16414

Operating parameters

Temperature monitoring range

 $0^{\circ}\text{--}49.9^{\circ}$ C, with $\pm~0.3^{\circ}$ C display accuracy and

0.1° C resolution

Pressure monitoring range (2 channels)

-45-990 mmHg

Alert range (each channel)

0-980 in 10 mmHg increments; default = 300 mmHg

Alarm range (each channel)

10-990 in 10 mmHg increments; default = 360 mmHg

Timers

Two digital timers (displaying hours, minutes and seconds) measure the duration of cardioplegia delivery and the time between deliveries.

Environmental conditions

Operating temperature

10°--40° C

Relative humidity

<95% relative humidity, noncondensing

For more information about the 8000 cardioplegia monitor, contact your Sarns representative or call **800/521-2818**. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

"Sarns" is a registered trademark of 3M.

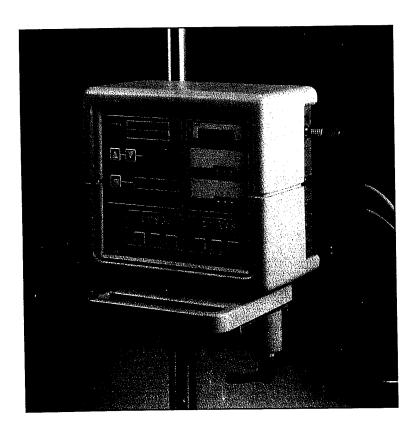
Sarns 3M Health Care

6200 Jackson Road, Ann Arbor, MI 48103 USA Phone: **800/521-2818** or 313/663-4145 FAX: 313/663-7981 Telex: 4930456 SARINC 3M

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Arterial monitor

Sarns 8000 modular perfusion system



Easy-to-watch integrated display for one pressure, three temperatures and two timers simplifies arterial monitoring.

two timers simplifies arterial monitoring. A well-organized control panel combines accurate digital displays with user-friendly membrane switches.

Convenient transducer connections for temperatures and pressure are made on the right side of the monitor. A flexible mounting arm positions the module according to personal preference.

User-set alerts and alarms warn of impending overpressure with visual and audio signals or actually stop the arterial pump. The system retains the settings and recalls them after the next power up.

Adjustable audio volume adequately warns users without startling them.

Arterial monitor specifications

Catalog number (Mounting arm ordered separately)

16413

Operating parameters

Temperature monitoring range (For YSI* 400-type probes)

 0° -49.9° C, with \pm 0.3° C display accuracy

and 0.1° C resolution

Pressure monitoring range

-45-990 mmHg

Alert range

0-980 in 10 mmHg increments: default = 300 mmHg

Alarm range

10-990 in 10 mmHg increments; default = 360 mmHg

Timers

Two independent timers, each with start, stop and reset switches, with hours, minutes and seconds

up to 9 hours, 59 minutes, 59 seconds.

Environmental conditions

Operating temperature

10°-40° C

Relative humidity

<95% relative humidity, noncondensing

*Yellow Springs Instrument Company, Yellow Springs, Ohio

For more information about the 8000 arterial monitor, contact your Sarns representative or call 800/521-2818. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

"Sarns" is a registered trademark of 3M.

Sarns 3M Health Care

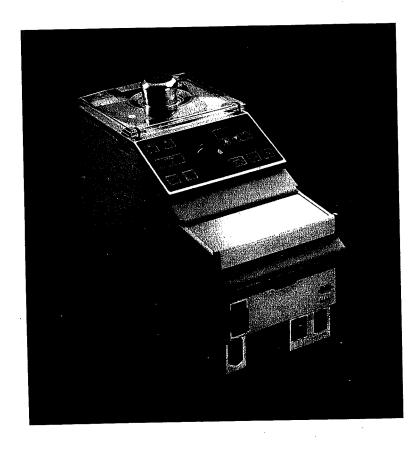
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© 3M 1993 Printed in USA Form No. 78-8067-6035-7

3M

Universal roller pump

Sarns 8000 modular perfusion system



Powerful portable pump consists of a microprocessor-controlled peristaltic pump in a spill-proof enclosure with its own power supply. The compact module has handles for easy lifting.

Accurate speed control from 1 RPM all the way up to 250 RPM and flow rates of 9.9 L/min. Response is excellent under a wide range of clinical conditions, temperatures and loads.

Precise digital readouts display flow rates in LPM or RPM. The pump automatically calculates and displays flow rates for various tubing sizes, including 4:1, 2:1 and 1:1 cardioplegia tubing. Helpful advisory information appears in the control panel message area.

On-the-fly occlusion adjustment permits fine tuning while the pump is running, yet allows quick tube removal if necessary. Interchangeable inserts for the tube clamps slide out easily for quick replacement.

Multiple checks of pump speed, including an accurate optical tachometer that measures pump speed directly from the drive shaft, quickly alert the operator to unlikely events such as overspeed, tachometer loss, pump jam or belt slip.

Intentional controls require that dual forward, reverse and computer switches be pushed simultaneously to ensure deliberate activation. The control panel is angled and color coded for maximum efficiency.

Cover interlock helps prevent spills into the pump head and pump jams because the pump operates only when the cover is closed.

Pump specifications

Electrical power

Voltage

115 V Pump 103.5-126.5 V~

(115 V, nominal)

220-240 V Pump

198-264 V~ (220-240 V, nominal)

100 V Pump 90-110 V (100 V. nominal)

Frequency

Current rating.

50/60 Hz

50,60 Hz

50/60 Hz

fully loaded system

Continuous flow

1.4 amps

0.7 amps

1.6 amps

Catalog numbers

Roller pump

16402

16407

16411

Physical description

Dimensions

Roller pump

Height Width Depth

8.2 in. (20,8 cm) 19.7 in. (50,0 cm) 14.0 in. (35,6 cm)

Weight

50 lbs. (22,6 kg)

Environmental conditions

Operating temperature

10°-40° C

Relative humidity

<95% relative humidity, noncondensing

For more information about 8000 modular roller pumps, contact your Sarns representative or call **800/521-2818**. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

"Sarns" is a registered trademark of 3M.

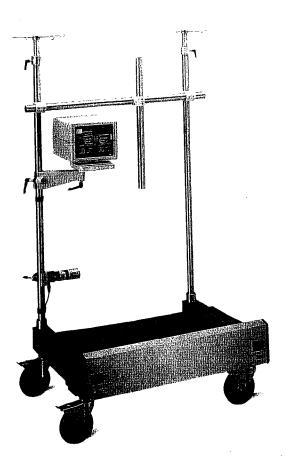
Sarns 3M Health Care

6200 Jackson Road, Ann Arbor, MI 48103 USA Phone: **800/521-2818** or 313/663-4145 FAX: 313/663-7981 Telex: 4930456 SARINC

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Pump base and safety monitor

Sarns 8000 modular perfusion system



Solid stainless-steel base with recessed top securely holds four or five modular pumps that can be exchanged quickly in an emergency. The removable polyethylene cover shields the unit from spills.

Unique safety monitor can be set to stop the designated arterial and cardioplegia pumps in the event of air detection or low reservoir level. An adjustable mounting arm offers maximum positioning flexibility.

Logical alerts and alarms combine audible and visual indications compatible with the seriousness of the situation. Activated alarms stop the arterial and cardioplegia pumps.

Protected power cords behind the front access door connect each pump to the base. All electrical connections are protected from spills but easily accessible behind the door.

Future expansion is always an option because the 8000 base is designed to integrate the modular components of the future. Be confident that each acquisition—from additional monitors to battery backup to electronic occluder—already has its place.

Sturdy poles make it easy to mount monitors and additional equipment.

After the monitor brackets are mounted, the monitors simply slide into place.

Superb maneuverability is assured by four easy-to-roll casters that can be locked to prevent rolling or swiveling.

Pump base specifications

Electrical power

Voltage

115 V Base 103.5-126.5 V~ (115 V, nominal) 220-240 V Base 198-264 V~ (220-240 V. nominal) 100 V Base 90-110 V~ (100 V, nominal) **Environmental conditions** Operating temperature Relative humidity

10°-40° C <95% relative humidity, noncondensing

Frequency

Current rating, fully loaded system 4-pump base 5-pump base

50/60 Hz

6 amps 7 amps

50/60 Hz

14 amps 16 amps

50/60 Hz

Catalog numbers 4-pump base

16400 16401 5-pump base 16422 Battery module

16409 16405 16410 16406 16415

Emergency power

The optional 8000 system battery module will power the arterial pump (operating in continuous mode). the monitors, occluder and lamp for 40 minutes. When the cardioplegia pump also is operating on battery power. the battery time available will decrease to 25 minutes.

Base

Depth

Dimensions Width

4-pump base 25.8 in. (65,5 cm) 33.3 in. (84.5 cm) 26.5 in. (67.3 cm)

5-pump base 25.8 in. (65,5 cm) 41.6 in. (105,6 cm) 26.5 in. (67,3 cm)

Extra poles and brackets

Description

Cross bar for 4-pump base (standard) ** Cross bar for 5-pump base (standard)

* * 2' pole (standard) 3' pole (optional)

4' pole (optional) Arm for mounting additional monitor Extension arm for extra pole

One included standard with 4-pump base. **One included standard with 5-pump base.

Catalog numbers

Safety monitor specifications

Description

Monitor, including mounting arm, standard with all bases

Catalog number

3/8 in. sensor

3/8 in. (9,5 mm) 1D x

3/32 in. (2.4 mm) wall

Detects bubbles of ≥ 1 mL at

Infrared air detection

Tubing requirement

Sensor performance

Catalog numbers

1/4 in. sensor 1/4 in. (6.4 mm) ID x

1/16 in. (1,6 mm) wall

Detects bubbles of ≥ 0.5 mL at flow rates up to 3 L/min in blood with a hematocrit

of 15-40%.

15020

flow rates up to 6 L/min in blood with a hematocrit

of 15-40%. 13540

Ultrasonic level detection

Level detection occurs when the fluid level in the reservoir is within ±0.2 in. (0.5 cm) from the horizontal center line of the level sensor pad.

Reservoir

Functions only with clear hard-shell reservoirs that have a wall thickness of 0.03-0.10 in. (0.8-2.5 mm).

Performance

Alert and alarm signals function properly with clear priming solutions or blood of any hematocrit.

Catalog numbers

Level sensor transducers Level sensor pads (20 sets/box) 16458601 16432901

For more information about the 8000 modular perfusion system, contact your Sarns representative or call 800/521-2818. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

"Sarns" is a registered trademark of 3M.

Sarns 3M Health Care

6200 Jackson Road, Ann Arbor, MI 48103 USA Phone: **800/521-2818** or 313/663-4145 FAX: 313/663-7981 Telex: 4930456 SARINC

^{*} Height from floor to top of roller pump when mounted on base.

Sarns 8000 modular perfusion system...

Build a Sarns 8000 perfusion system by selecting components to suit your patient safety, clinical performance and budget needs...now and in the future.

In standard configuration, your system will:

- Pump blood using roller or centrifugal pump technology in a four- or fivepump configuration.
- Detect gross air bubbles and stop the arterial and cardioplegia pumps under specific alarm conditions.
- Warn when the rigid reservoir blood levels reach an operator-set minimum and stop the arterial and cardioplegia pumps under specific alarm conditions.
- Accommodate auxiliary equipment through two outlets, one of which is switched to safety systems.
- Allow retrofitting of additional capabilities after purchase.

With optional capabilities, your 8000 system will:

- Monitor arterial pressure, three temperatures and two times.
- Display two cardioplegia pressures, three temperatures and two times.
- · Control venous line occlusion.
- Supply uninterrupted backup power for two pumps and all safety systems for 25 minutes.

Set more information about the 8000 modular perfusion system, confact your local Sans representative or all 800/521-2818, intelligency at 23 3063-4145

Secondaria insert for indications, contraindications,

Series and Delphin are registered trademarks of 3M.

Sarns 3M Health Care

8200 Jackson Road Ann Arbor, MI 48103 USA Phone: 800/521-2818 or 313/663-4145 FAX: 313/663-7981 Talext 4930456 SARINC

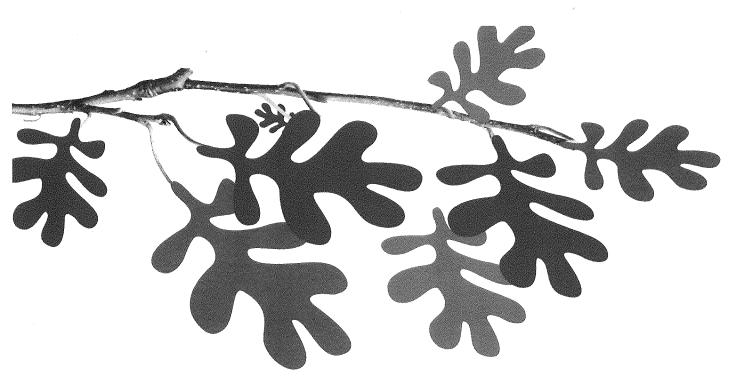
8 3M 1983. Printed In USA: Form No. 78-8067-6023-3

REPLACEMENT



Extracorporeal Excellence





OUR FIFTH-GENERATION MODULAR HEART-LUNG MACHINE HAS COMPLETELY REWRITTEN THE STANDARDS FOR FUNCTIONALITY, FLEXIBILITY AND QUALITY.

The S5™ is in a class by itself. The innovation represents the culmination of more than 30 years of experience in extracorporeal perfusion system design and manufacturing. Its solid construction and sophisticated feature set reflect input from professionals operating in real world conditions.

For the perfusionist who demands intelligent, functional ergonomics and reliable safety systems, the S5 delivers. Its refined modular design permits the quick and easy exchange of individual components in even the most challenging of environments. Software based upgrades that can be implemented at any time will allow your system to remain state-of-the-art for many years to come.

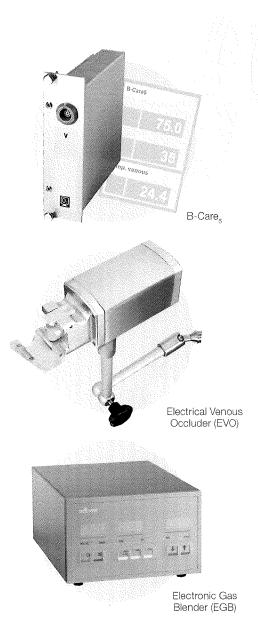
From a small, compact HLM equipped with three roller pumps to a full-featured system with seven roller pumps and the full range of control and monitoring functions, the S5 can be configured according to your individual requirements and budget considerations.

The renowned integrated Centrifugal Pump (SCP) and Electronic Remote-controlled Tubing Clamp (ERC®) can be easily integrated into the S5 without consuming a console position. All S5 safety controls can then be applied to the SCP.

The S5 is now available with pulsatile flow capability for both the roller and centrifugal pumps.

The high performing and quiet 3T heater/cooler, Electronic Gas Blender, Electronic Venous Occluder and B-Care, Sat/Hct monitor can be remotely controlled and/or monitored from the control panel of the S5.

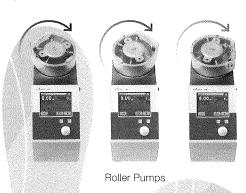




ERGONOMICS

In today's OR, available space is at a premium, which is why we've designed the S5 with 20% smaller outward dimensions as compared to the SIII.

The angled pump displays, flexible mast system and other available options for mast mounting will ensure that your pump can be optimized to exceed your ergonomic needs.

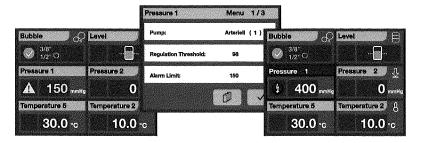


QUALITY AND DURABILITY

Optimizing operational safety was paramount in the design of S5. Only parts made of the highest quality materials with the lowest failure rates and greatest possible resistance to wear and tear are used. The care taken in the selection of the materials and parts used contributes to reducing the operating costs and increasing the durability of the system.

Sorin Group is a leader in the innovation of cardiovascular perfusion products. Our unsurpassed manufacturing experience and customer-driven design excellence will ensure that your investment meets your highest expectations in quality, performance, safety and simplicity.

Control Panel Views



SAFETY

All of the warnings and automated alarms of the S5 system—some of which are acoustically differentiable—are recorded and listed chronologically on the system display. All pertinent information is clearly displayed, and critical situations can be quickly detected and cleared.

In the event of power failure, the uninterruptible power supply (UPS) enables further operation for up to 130 minutes. The remaining time is continually indicated on the battery status display.

TECHNOLOGY

Micro processors contained within the various modules ensure that each component functions as designed, in real-time. In addition, each module is completely replaceable and interchangeable.

No other perfusion system can match S5's new, high-resolution TFT displays. This new technology enables the perfusionist to easily view displayed values from greater distances and at an angle of up to 140 degrees.

The menu system is clearly structured and guides you quickly and intuitively through the set-up menus to the desired touchscreen display. The use of descriptive system displays eliminates guesswork and makes the perfusionist's job easier.

The brushless, direct-drive motor of the roller pumps runs extremely quiet. Speed adjustments are performed via an incremental encoder. The technology is maintenance-free, assuring lower operating costs.

FLEXIBILITY

The S5 was designed to meet the diverse needs of today's hospital—while keeping pace with changing demands.

It can be operated with as few as three and as many as seven roller pumps and a centrifugal pump. Two newly developed mast roller pumps (150 mm or 85 mm diameter) enable positioning in close proximity to the patient. The pump heads can easily be rotated through a range of 180 degrees and self-lock into position for convenient optimization of the tubing circuit.

The S5 mast system consists of three vertically and one horizontally moveable mast for mounting external devices and disposables.

DATA MANAGEMENT SYSTEM

The Data Management System (DMS) offers a new standard of convenience for the surgical team. The fully integrated system with its easy-to-use interface provides valuable tools for conducting correlation studies or trends analysis and managing the perfusion record.

Each of the system's components work to help you achieve excellent performance, as well as an unprecedented level of convenience.

DATAPAD® TOUCH SCREEN

DataPad is a drip proof, medical grade tablet PC mounted directly on the Sorin perfusion system. The touch screen interface enables fast and easy manual entries without use of a keyboard or mouse.

DMS CHARTING SYSTEM

DMS automatically records all values and events of the heart-lung machine and external devices (e.g. patient monitor, blood gas analyzer, ACT meter and cerebral oximetry). This innovative charting system can also provide data storage for all hospital operating rooms in one central database, thereby avoiding inconsistent data inventory and enabling data compilation for studies and analysis. Data transfer is provided in different formats for easy processing in other programs (Excel, Access, dBase, etc.).

DMS is HL7 compatible to align perfusion data with Electronic Health Record compliance.



ORDERING INFORMATION

Product	Section breaking the con-	("Nething)	Deposition and
S5 Consoles with E/P Pack and Standard Mast System		SCP Centrifugal pump system (for S5 system exclusively)	60-00-50
S5 Console 3 position	48-30-00	SCP Drive unit	60-01-00
S5 Console 4 position	48-40-00	SCP Control panel	60-02-50
S5 Console 5 position	48-50-00	Emergency hand crank	60-01-50
S5 System Components		Flow sensor 3/8"	96-414-120
S5 3-slot system panel	28-95-03	ERC Electrical Remote-Controlled	60-05-60
S5 4-slot system panel	28-95-00	tubing clamp	
S5 5-slot system panel	28-95-01	Electronic Gas Blender (EGB)	25-28-67
S5 6-slot system panel	28-95-04	Electronic Venous Occluder (EVO)	12-80-00
S5 Control and display module	28-95-10	B-Care _s Sat/Hct Monitor	25-60-00
S5 Blank module	28-95-30	DMS with Server and Online License	24-10-90
S5 Roller pump 150 (S5 RP 150)	10-80-00	DMS with Online License	24-10-95
S5 Double roller pump 85 (S5 DRP 85)	10-85-00	S5 Pressure sensor module	22-20-20
_arge S5 mast roller pump 150	50-80-00	(2-channel)	
S5 Mast roller pump 85 (S5 MRP 85) includes 1 pump and control panel	50-80-70	S5 Temperature sensor module (4-channel)	20-30-20
2 S5 Mast roller pump 85	50-80-60	S5 Level sensor module, complete	23-40-00
(2 S5 MRP 85) includes 2 pumps	00 00 00	Holder for level sensor	75-521-548
and control panel		S5 Bubble sensor module, complete	23-45-00
2 S5 Mast roller pumps 85 with	50-80-62	S5 Cardioplegia sensor module	27-80-20
coupling (2 S5 MRP 85)		S5 Interface module with 4 serial	29-02-50
S5 Mast extension system	50-45-00	ports, RS-232	
includes telescoping mast, 2 sets of horizontal joining arms, short vertical		S5 Shelf 3 position	48-31-10
mast locking arm for transport		S5 Shelf 4 position	48-41-10
S5 Tubing clamp "Variolock" RP 150	10-81-30	S5 Shelf 5 position	48-51-10
(included with RP 150)	.5 51 55	S5 LED lamp	35-05-60

This brochure was printed on recycled paper.







Via E-Mail: ggriffin@unch.unc.edu

September 29, 2014

Mr. Greg Griffin CCP Chief Perfusionist University of North Carolina Hospital 101 Manning Drive Chapel Hill, NC 27514 Account: 910778

Contract Number: OP91077820140120,2

RE: S5 Heart Lung Perfusion System Outright Purchase Proposal

Dear Mr. Griffin:

As requested through Adam Clark, the Sorin Group USA, Inc. Account Executive in your area, we are pleased to make the following proposal for the S5 Heart Lung Perfusion System. This proposal will become invalid if not accepted by December 29, 2014.

Our terms are Net 30, and Sorin Group USA, Inc. prepays freight and adds to the invoice. This proposal is confidential between Sorin Group USA, Inc. and University of North Carolina Hospital ("Customer"), and disclosure of the information it contains will render it null and void. Notwithstanding the foregoing, this proposal may be disclosed to such representatives, advisors and affiliates of Customer as have a need to know such information for the sole purpose of assisting Customer in evaluating the proposal, and for no other purpose (it being understood that such representatives, advisors and affiliates shall be informed by Customer of the confidential nature of such information and shall be directed by Customer and shall agree to treat such information confidentially).

If you accept the terms and conditions (see attached Standard Terms and Conditions) of this proposal for the purchase of the quoted equipment, please fax or mail your Purchase Order referencing your contract number on the Purchase Order to the undersigned, Fax No. (303) 467-6590. The mailing address is referenced in the terms and conditions under ordering information.

EQUIPMENT SERVICE:

Upon expiration of the warranty provided with your equipment, extended service coverage is available. The current annual rate for the equipment quoted is \$15,699.00. If purchased at the time of the equipment, an additional 10% discount is offered on the current annual service rate. Additional discounts are also available for multiple year service coverage. Please contact the undersigned for a multiple year service coverage quote.

Our records indicate that you are not affiliated with a GPO (Group Purchasing Organization) member with whom Sorin Group USA, Inc. currently has a pricing arrangement. If this is incorrect, please note your GPO membership in the spaces provided and fax to (303) 467-6590. This will help Sorin Group USA, Inc. to determine that the pricing we have established does not exceed pricing we have negotiated with your GPO. If you are a member of more than one GPO, please note your commitment for pricing for all the GPO contracted items for purchase from Sorin Group USA, Inc.



We welcome the opportunity to supply and support your equipment needs in the coming years. If you have any questions or if I can be of any further assistance, please contact me at (800) 221-7943, extension 6180, or Adam Clark, voice mailbox # 5015.

Sincerely,

Sorin Group USA, Inc.

Sarany L. Sadler

Tammy L. Sadler

Senior Contract Administrator

Enclosure

cc: Mr. Adam Clark, Sorin Group USA, Inc. Senior Account Executive

Mr. Ted Cowles, Sorin Group USA, Inc. Regional Manager



September 29, 2014

S5 HEART LUNG PERFUSION SYSTEM OUTRIGHT PURCHASE PROPOSAL FOR

University of North Carolina Hospital in Chapel Hill, NC

S5 HEART LUNG PERFUSION SYSTEM:

Catalog No.	Description	Quantity Per System
300 3230 000	S5 Consoles	
48-30-00	3-Pump console (includes: Timer, power supply, emergency power supply, electronic and power supply pack and mast system)	1
45-09-10	Cable holding and organizing system	1
45-09-11	Cable holding and organizing system	1
43-42-61	Cap for fast clamp (6 pcs.)	1
	S5 Pump Modules	
10-80-00	Single roller pump	3
50-80-00	Mast Roller Pump 150 (incl. mast mountable pump and control panel)	2
10-84-60	Pump Tray for RP150	1
10-84-64	Double Pump Tray	1
50-45-15	Mast Extension Pole	1
50-80-99	Color Knob Set	1
	Variolock Tubing Gate and Accessories	
10-81-30	Tubing Gate	5
10-61-94	Tubing Variolock 4:1 SILVER	1
	S5 Control Desk	
28-95-00	4-slot system Panel	1
28-95-00	4-slot system Panel – for existing system	1
28-95-10	Display Module	4
28-95-10	Display Module – for existing system	i
20 /0 10	S5 Control Devices and Monitors	1
22-20-20	Pressure sensor module (2 channel)	1
20-30-20	Temperature sensor module (4 channels) for YSI probes	1
23-40-00	Level Sensor (incl. 23-27-40, 23-27-41)	1
75-521-548	Holder (required for Level Sensor II 23-27-40)	1
23-27-60	Mounting pads, Level sensor II	1
23-45-00	3/8" Bubble sensor module w/420 mm holder, incl. (23-07-50, 23-26-96, 23-45-20 and 96-06-10)	1
10-07-48	Tubing insert, metal, 3/8 X 3/32, BLUE	1
27-80-20	Cardioplegia Sensor Module	1
23-07-40	1/4 Bubble Sensor (pediatric or Cardioplegia)	i
10-07-45	Tubing insert, metal, 1/4 x 1/16, RED	1
	S5 Accessories - Masts and Crosstrays	
48-31-19	Crosstray 3 Position w/Power Outlet	1
	Venous Line Occluders	
12-80-00	Electronic Line Clamp (incl. 12-80-10 & 28-95-70)	1
12-80-00	Electronic Line Clamp (incl. 12-80-10 & 28-95-70) – for existing system	1
	S5 Miscellaneous	
35-05-70	Led Lamp 24V	1
0264-2049	Abbott Transpac IV Pressure Transducer Cable	3
29-02-70	S5 One Port Interface Module	1
10-07-49	Tubing insert, metal, 1/2 x 1/16, SILVER	1
10-07-43		6220 246 00%
	Net Price for All Equipment	\$239,346.00*
	Freight Charges Per System	\$980.00
	Extended Amount for Each System with Freight	\$240,326.00*

^{*}Price does not include applicable taxes.



SORIN GROUP USA, INC. STANDARD TERMS AND CONDITIONS

	STANDARD TERMS AND CONDITIONS
PRICE & PAYMENT	Payment terms subject to approved credit. Taxes, if owed, shall be added to the invoice amount. Tax
TERMS:	exemption certificates must be submitted to Sorin Group USA, Inc. prior to placement of orders. All prices
	are subject to an annual increase set by Sorin Group USA, Inc. at its sole discretion. Credit cards will not be
	accepted for payment of amounts owed.
METHOD OF	Equipment and Disposable Products shall be shipped and delivered to Customer via surface transportation.
SHIPMENT AND	Sorin Group USA, Inc. prepays freight and adds to the invoice. Freight charges for Equipment may be billed
FREIGHT:	to the Customer separately.
TITLE & RISK OF LOSS:	Title of, and risk of loss to, Equipment and/or Disposables shall transfer to Customer upon shipment.
ORDER QUANTITIES:	Made to order, custom packs require a minimum order quantity of one case. Federal regulations prohibit the sale of incomplete case quantities.
RETURNED GOODS:	Returned goods will be accepted only with prior written authorization from Sorin Group USA, Inc. and in accordance with such authorization. Items must be returned freight prepaid and accompanied by Sorin Group USA, Inc.'s Returned Materials Authorization form. Items to be returned must be in ORIGINAL UNOPENED cartons, have original labels, be in a saleable condition and are subject to a twenty-five percent (25%) re-stocking charge. Goods held over twelve (12) months from the date of invoicing, abused or custom items, chemical concentrates, and items identified as non-returnable or that have deteriorated due to a cause beyond Sorin Group USA, Inc.'s control, may not be returned.
DAMAGED	Damage or shortage should be noted on the freight bill. If damage is observed after opening, notify the
SHIPMENTS:	transportation company and request a hidden damage report . No adjustment, credit or duplicate shipment can be made until written documentation is received by Sorin Group USA, Inc.
CRDERING INFORMATION:	For a period of twelve (12) months from the date of installation of Equipment, Sorin Group USA, Inc. will at its option repair or replace (free of charge) Equipment that Sorin Group USA, Inc. finds defective in materials or workmanship. For a period of twelve (12) months from the date of the invoice, Sorin Group USA, Inc. will replace (free of charge) Disposable Products which Sorin Group USA, Inc. finds defective in materials or workmanship. For a period of ninety (90) days from the date of the invoice, Sorin Group USA, Inc. will repair or replace (free of charge) spare parts that Sorin Group USA, Inc. finds defective in materials or workmanship. Sorin Group USA, Inc. is not responsible for, and shall have no obligation with respect to, any failure caused by normal wear and tear, misuse, unauthorized alterations, accident, neglect, use of nonstandard accessory attachments, and/or improper maintenance. Sorin Group USA, Inc. does not verify the safety or efficacy, and makes no warranties - expressed or implied - with respect to any non- Sorin Group USA, Inc. components included at Customer's request or any components or products used other than as expressly intended by their manufacturer. THIS LIMITED WARRANTY CONTAINS THE CUSTOMER'S EXCLUSIVE REMEDIES. SORIN GROUP USA, INC. SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING FROM THE USE OF ITS PRODUCTS. SORIN GROUP USA, INC. DOES NOT GIVE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, Orders may be placed by phone, facsimile, e-mail or mail to Sorin Group USA, Inc. at: Sorin Group USA, Inc. Attn.: Customer Service Department 14401 W. 65th Way Arvada, Colorado 80004-3599 (800) 650-2623 Toll-Free Phone (800) 323-4031 Fax
	Normal business hours are 6:00 a.m. to 5:00 p.m., MST, Monday through Friday. Purchase Order numbers
DELIVERY:	are required at the time the order is placed. Stock products will be delivered in 7-10 days after receipt of order (ARO). Equipment orders will ship 8-10 weeks ARO.
DISTRIBUTORS:	Sorin Group USA, Inc. is not responsible for any fees associated with placement of orders through JIT suppliers, distributors, or warehouses.
MODIFICATION AND	Customer shall not modify or alter the products in any way without the prior written approval of Sorin Group
LEGAL	USA, Inc. Customer shall conduct its business in compliance with all applicable laws, statutes and
COMPLIANCE	ordinances and shall comply with all applicable governmental rules and regulations in force with respect to
	the products.
SUBSTITUTION:	Sorin Group USA, Inc. reserves the right to discontinue products that may be covered by this Agreement. Should any product covered by this Agreement become obsolete during the term of this Agreement, Sorin Group USA, Inc. will notify the Customer and offer substitute product, if available.
FORCE MAJEURE:	Sorin Group USA, Inc. shall not be liable for any delays in delivery from any cause beyond its control including, without limitation, acts of GOD, fire, flood, strike, lockout, factory shutdown, supply shortage, priority request, riot, war or embargo. In the event of shortage of supply of materials or goods for any reason, Sorin Group USA, Inc. may allocate its available supply among itself and its Customers in a manner determined by Sorin Group USA, Inc. in its sole discretion.



PAST DUE ACCOUNTS:	Customer shall pay Sorin Group USA, Inc. the lesser of interest at the rate of one and one-half percent (1.5%) per month or the highest rate permitted by applicable law on all invoices thirty (30) days past due. Customer agrees to pay all reasonable attorneys' fees and expenses incurred by Sorin Group USA, Inc. in enforcing its rights hereunder.
PRODUCT TRACEABILITY:	Customer is responsible to maintain product traceability for each individual product delivered by Sorin Group USA, Inc. Customer will comply with any product recalls initiated by Sorin Group USA, Inc. and will notify Sorin Group USA, Inc. of any Customer complaints on Sorin Group USA, Inc.'s products.
DISCOUNTS FROM LIST PRICE:	The parties understand that for purposes of 42 C.F.R. § 1001.952(h), any reduction in the amount charged Customer from list price is a "discount or other reduction in price" to Customer. The Customer shall report the discount or reduction in price and provide other requested information to any state or federal program which provides cost or charge-based reimbursement to Customer for products and supplies covered by this Agreement in accordance with applicable governmental regulations.
INDEMNIFICATION:	Customer agrees to hold Sorin Group USA, Inc., and its employees, officers, directors, agents, successors and assigns harmless from and against any and all losses, claims and damages (including reasonable fees and expenses of counsel), as they are incurred, which arise out of or are related to any claim by a third party of personal injury or other loss to the third party caused by alleged negligence on the part of the Customer or its employees, agents, or assigns. This provision shall survive expiration or termination of this Agreement.
TERM:	Unless there is a specific termination provision in a document signed by Customer and Sorin Group USA, Inc., Sorin Group USA, Inc., Sorin Group USA, Inc. may terminate this Agreement and its obligations to Customer at any time upon one hundred twenty (120) days advance written notice to Customer and immediately upon written notice to Customer if Customer fails to pay Sorin Group USA, Inc. when due any amount it owes Sorin Group USA, Inc. or otherwise breaches these Standard Terms and Conditions. Termination or expiration of this Agreement shall not affect Customer's obligation to pay Sorin Group USA, Inc. all amounts it owes Sorin Group USA, Inc. (including interest and attorneys' fees) nor shall it affect any provision intended to survive expiration or termination.
STANDARD TERMS AND CONDITIONS:	These Standard Terms and Conditions supersede any provisions, terms and/or conditions contained in any purchase order or other writing submitted by Customer to Sorin Group USA, Inc. and the provisions, terms and/or conditions of any such purchase order or other writing submitted by Customer are of no force or effect. These Standard Terms and Conditions shall be construed and enforced in accordance with the laws of the State of Colorado.

ADDITIONAL INFORMATION REQUIRED FOR EQUIPMENT TO BE SHIPPED TO CUSTOMER'S LOCATION

Customer Contact Information Department Phone Contact name Alternate Contact Shipping/Receiving Perfusion/Surgery/ECMO O.R. Director Biomedical Engineering Purchasing **Customer Shipping Information** Customer PO Number: ____ Facility Medical License Number: **Equipment Shipping Address:** Hospital Name Street Address State Zip Appointment Required
Inside Delivery Lift gate Other (Please describe)

Please include these special delivery instructions requirements on your Purchase Order.



GPO Membership Confirmation For University of North Carolina Hospital in Chapel Hill, NC Account: 910778

GPO Membership Commitment (Please note that SORIN GROUP USA, INC. currently has	
contracted pricing only with the GPO's listed below). Please choose only one, if applicable.	(Buyer: Full Corporate Name)
	(Signature)
Carolina Shared Services	(Name - Please Print or Type)
Cooperative Services of Florida	
☐ HCA (Hospital Corporation of America)	(Title)
HPA (Healthcare Purchasing Alliance)	(Date)
☐ HPG (HealthTrust Purchasing Group)	
Premier	
PSCS (Providers Supply Chain Services)	·

You only need to complete and return this page if Sorin Group USA, Inc. does not have your correct GPO affiliation on the cover page. Please complete the above information and fax this page to (303) 467-6590.

Exhibit 4

7. Specialized Cardiac Services (for questions, call 855-3865 [Medical Facilities Planning])

(a) Cardiac Catheterization	Diagnostic Cardiac Catheterization ICD-9 37,21, 37.22, 37.23, 37.25	Interventional Cardiac Catheterization ICD-9 00.66, 99.10, 36.06, 36.07, 36.09; 35.52, 35.71, 35.96
1. Number of Units of Fixed Equipment	3HDULT +	- 1 PEDIATRIC
Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger	121	104
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	1467	996
4. Number of Procedures* Performed in Mobile Units		
	37.77, 37.79, 37.80, 37.8	.9 0, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 1, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 7, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53,
5. Number of Units of Fixed Equipment	2	
6. Number of Procedures on Dedicated EP Equipment	/02	7

*A procedure is defined to be one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. Count each visit once, regardless of the number of diagnostic, interventional, and/or EP catheterizations performed within that visit.

Name of Mobile Vendor: NONE: REMOVES 94/12

Number of 8-hour days per week the mobile unit is onsite: O 8-hour days per week.

(Examples: Monday through Friday for 8 hours per day is 5 8-hour days per week. Monday, Wednesday, & Friday for 4 hours per day is 1.5 8-hour days per week)

(b) Open Heart Surgery	Number of Machines/Procedures
1. Number of Heart-Lung Bypass Machines	4
2. Total Annual Number of Open Heart Surgery Procedures Utilizing Heart-Lung Bypass Machine	44/
3. Total Annual Number of Open Heart Surgery Procedures done without utilizing a Heart-Lung Bypass Machine	36
4. Total Open Heart Surgery Procedures (2. + 3.)	477
Procedures on Patients Age 14 and younge	ľ
5. Of total in #2, Number of Procedures on Patients Age 14 & younger	110
6. Of total in #3, Number of Procedures on Patients Age 14 & younger	//

PROPOSED TOTAL CAPITAL COST OF PROJECT

A.	Site Costs				
	(1) Full purchase price of land		\$ 0		
	Acres Price per Acr	e \$	•		
	(2) Closing costs		\$ 0		
	(3) Site Inspection and Survey		\$ 0		
	(4) Legal fees and subsoil investigation		\$ 0		
	(5) Site Preparation Costs				
	Soil Borings	\$	0		
	Clearing - Earthwork	\$	0		
	Fine Grade for Slab	\$	0		
	Roads - Paving	\$	0		
	Concrete Sidewalks	\$	0		
	Water and Sewer	\$	0		
	Footing Excavation	\$	_ <u>_</u>		
	Footing Backfill	\$	0		
	Termite Treatment	\$	0		
	Other (Specify)	\$	 0		
	Sub-Total Site Preparation Costs	Ψ	<u> </u>		
	(6) Other (Specify)		\$ 0		
	(7) Sub-Total Site Costs		\$	0	
В	Construction Contract		Ψ		
D.	(8) Cost of Materials				
	General Requirements	\$	0		
	Concrete/Masonry	\$	<u> </u>		
	Woods/Doors & Windows/Finishes	\$	0		
	Thermal & Moisture Protection	\$	0		
	Equipment/Specialty Items	Ψ \$	0		
	Mechanical/Electrical	\$	_		
	Other (Unit Strut Support)	\$ \$	0		
	Sub-Total Cost of Materials	Ψ	<u> </u>		
	(9) Cost of Labor		\$ 0		
			\$ 0		
	. (10) Other (Specify) Firestopping		\$ <u>0</u> \$0		
	Asbestos Abatement		\$0		
	Window Upgrade		\$0		
	HVAC Upgrade		\$0	0	
_	(11) Sub-Total Construction Contract	Į.	\$	0	
Ċ.	Miscellaneous Project Costs				
	(12) Building Purchase		\$0		
	(13) Fixed Equipment Purchase		\$0		
	(14) Movable Equipment Purchase		\$ <u>240,326</u>		
	(15) Furniture		\$0		
	(16) Landscaping	*	\$0		
	(17) Consultant Fees	Φ.	0		
	Architect and Engineering Fees	\$	0		
	Legal Fees	\$	_0		
	Market Analysis	\$	_0		
	Other (Structural fee)	\$	_0		
	Other (Specify) Sub-Total Consultant Fees	\$	_0		
		oto \	\$0 \$ 0		
	(18) Financing Costs (e.g. Bond, Loan, (19) Interest During Construction	- 10.)			
	(20) Other (Specify)		\$0 \$ 0		
	(20) Other (Specify) (21) Sub-Total Miscellaneous			240,326	
	(22) Total Capital Cost of Project (Su	m A.C ah		40,020	\$ 240,326
	(AA) Total Supital Sout of Froject (Sulli A-S above)				Ψ <u> </u>

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

Signature of Licensed Architect or Engineer

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

Oct 2 2014

Assistant Director of Operations
(Title & Signature of Office Authorized to Represent Provider/Company)